

# **EXHIBIT**

## **E**

Steven A. Zalesin (SZ 0901)  
Jeffrey I.D. Lewis (JL 8335)  
Scott B. Howard (SB 1932)  
PATTERSON, BELKNAP, WEBB & TYLER LLP  
1133 Avenue of the Americas  
New York, New York 10036  
Telephone 212-336-2000, Facsimile 212-336-2222

*Attorneys for Plaintiff*

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

JOHNSON & JOHNSON,

Plaintiff,

v.

THE TRUSTEES OF COLUMBIA  
UNIVERSITY IN THE CITY OF NEW YORK,

Defendant.

Case Number: 03 CV 8811

COMPLAINT

Filed 11/6/03

Plaintiff Johnson & Johnson ("J&J"), by its attorneys Patterson, Belknap, Webb & Tyler LLP, for its Complaint against defendant The Trustees of Columbia University in the City of New York ("Columbia"), alleges as follows:

**Nature of Action**

I. More than 20 years ago, Columbia obtained the first of several United States patents on an invention relating to recombinant DNA technology called "cotransformation." These patents are based upon work funded by the United States Government.

2. In 2002, two years after the expiration of those patents, Columbia obtained another patent on the same technology, and is now attempting to use this new patent improperly to extend its monopoly an additional 17 years.

3. J&J brings this action to prevent Columbia from recapturing technology that has already been placed in the public domain.

#### **Background**

4. In 1983, the United States Patent & Trademark Office ("PTO") issued Columbia its first patent on the contranformation technology. The PTO issued two additional patents in 1987 and 1993. In order to obtain these later patents, Columbia was required to file a "terminal disclaimer" in which it surrendered the term of the additional patents beyond the expiration of the first patent. Each of those three patents (the "Axel patents") expired on August 16, 2000.

5. Upon information and belief, in the past 20 years, Columbia has licensed the Axel patents to more than two dozen companies. This included a December 14, 1989 agreement between J&J and Columbia ("License Agreement"). Pursuant to the License Agreement, J&J has paid Columbia millions of dollars in royalties for the right to use the Axel patents.

6. Over the 17-year life of the Axel patents, Columbia has obtained the full benefit of its patent coverage. It has earned nearly \$400 million in royalties payable under licenses for the Axel patents.

7. The expiration of the Axel patents in 2000 placed the technology into the public domain. However, two years later in 2002 Columbia obtained a fourth patent – U. S. Patent No. 6,455,275 (the "'275 patent"). Unlike the two previous patents, Columbia obtained this fourth patent without filing a terminal disclaimer. On the basis of this new patent, Columbia

seeks to extract from J&J (and upon information and belief, nearly every other biopharmaceutical company) additional royalties until the expiration of the '275 patent in 2019. This withdrawal of technology from the public domain is improper and violates the patent laws.

8. J&J brings this action for a declaration that the '275 patent is invalid and unenforceable.

#### **Parties**

9. Plaintiff Johnson & Johnson is a corporation organized and existing under the laws of New Jersey, having a principal place of business in New Brunswick, New Jersey.

10. Through its wholly-owned subsidiaries, including Ortho Biotech Products, L.P. ("Ortho Biotech"), J&J develops, manufactures and markets biotechnology-derived products. Among the products manufactured and marketed by Ortho Biotech is recombinant human erythropoietin ("EPO"), a biotechnology-derived protein that corrects anemia by stimulating the body to produce red blood cells.

11. Upon information and belief, defendant Columbia is a corporation organized and existing under the laws of the State of New York and having a principal place of business in New York, New York.

#### **Jurisdiction**

12. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), 2202 and the Court's supplemental jurisdiction under 28 U.S.C. § 1367(a). Also, because the amount in controversy exceeds \$75,000, and this action is between citizens of different states, this Court has jurisdiction under 28 U.S.C. § 1332(a)(1).

#### **Venue**

13. Venue is proper in this district under 28 U.S.C. §§ 1391(a), (b) and (c).

**Facts**

***Columbia Obtains Its Original Three Patents***

14. On February 25, 1980, Columbia filed U.S. Patent Application 06/124,513 (the "'513 application"), the first cotransformation technology patent application. The invention described and claimed in the '513 application was the result of work that was funded by the U.S. Department of Health and Human Services ("HHS"). The '513 application led to the issuance of several patent, each of which was assigned to Columbia.

15. The first patent was U.S. Patent No. 4,399,216 (the "'216 patent"). The named inventors of the '216 patent are Richard Axel, Michael H. Wigler and Saul J. Silverstein. The '216 patent issued on August 16, 1993 and expired on August 16, 2000. A true and correct copy of the '216 patent is attached hereto as Exhibit A.

16. The second patent was U.S. Patent No. 4,634,665 (the "'665 patent"). It issued on January 6, 1987. The '665 patent has an identical disclosure to the '216 patent. In order to obtain allowance of the '665 patent, Columbia filed a terminal disclaimer disclaiming its term beyond the August 16, 2000 expiration date of the '216 patent. A true and correct copy of the '665 patent is attached hereto as Exhibit B.

17. The third patent is U.S. Patent No. 5,179,017 (the "'017 patent"). It issued on January 12, 1993. Like the '665 patent, the '017 patent has an identical disclosure to the '216 patent. And like the '665 patent, in order to obtain allowance of the '017 patent, Columbia filed a terminal disclaimer disclaiming its term beyond the August 16, 2000 expiration date of the '216 patent. A true and correct copy of the '017 patent is attached hereto as Exhibit C.

18. Upon information and belief, from the issuance of the first patent in 1983 until their expiration in 2000, Columbia profited enormously from these patent, obtaining hundreds of millions of dollars in royalties.

***Columbia's Failed Lobbying Attempt to Extend the Axel Patents***

19. The '216, '665 and '017 patents were due to expire in August 2000. In an attempt to extend its patent monopoly beyond its 17-year grant, Columbia vigorously pursued special legislation from Congress extending the term of the '216 patent.

20. Upon information and belief, in 2000 Columbia attempted to bury the patent term extension in an Agricultural Appropriations Bill. However, as a result of protests by the public, the patent term extension measure was removed from the Agricultural Appropriations Bill.

21. Upon information and belief, in 2000 Columbia also attempted to include a similar measure in the Department of Defense Appropriations Act. However, like with the attempt to obtain an extension in the Agricultural Appropriations Bill, the extension was removed from the final version of the Act.

22. Without obtaining Congressional approval for a patent term extension, the '216, '665 and '017 Axel patents expired on August 16, 2000 and entered the public domain.

***Columbia Obtains the '275 Patent***

23. Just before the issuance of the '017 patent, Columbia submitted the first of a chain of patent applications that eventually led to the issuance of the '275 patent. The first patent application was filed in 1992, the second in 1994 and the third in 1995. Importantly, the fourth and final application in the chain was filed on June 7, 1995. After nearly a decade of secret prosecution, that application eventually issued as the '275 patent in 2002.

24. The filing date of the fourth application on June 7, 1995 was of critical importance. Pursuant to the GATT amendments – which took effect on the following day – the term of patents was changed from 17 years from issuance to 20 years from filing. Had the '275 patent been filed a day later, it would have expired in February 2000 – 20 years from its effective

filing date. However, as a result of it being filed on June 7, Columbia had the potential for an additional 17-year monopoly from issuance. Because the '275 patent's term would be measured from its issue date and not its filing date, Columbia had no incentive to prosecute its application with reasonable dispatch. Instead, it has had every incentive to delay its prosecution in order to maximize its patent monopoly. Columbia did just that, and its dilatory prosecution tactics resulted in an unreasonable delay.

25. Like the '665 and '017 patents, the '275 patent is based on the identical disclosure as the '216 patent. However, unlike the '665 and '017 patents, the '275 patent does not include a terminal disclaimer. Thus, while the issuance of the '665 and '017 patents did not extend the time of Columbia's monopoly power, the '275 patent resulted in an unfair and unwarranted time-wise extension of patent rights. A true and correct copy of the '275 patent is attached hereto as Exhibit D.

***HHS Limits Columbia's Right To Exploit the Axel Patents***

26. The research that led to the original patent application was funded by grants from HHS. As a result of that funding, HHS imposed restrictions on Columbia's rights under the patents. While the HHS granted Columbia title to the patents, it imposed several conditions, including the requirement that any license "shall include adequate safeguards against unreasonable royalties and repressive practices."

***Columbia Demands Payment of Royalties Based On Expired Patents***

27. As set forth above, J&J and Columbia are parties to a License Agreement concerning the Axel patents. Among other things, the License Agreement specifies the terms upon which J&J is required to pay royalties to Columbia based upon J&J's activities within the United States in connection with EPO, which activities otherwise would infringe the Axel patents.

28. Prior to the expiration date of the three, original Axel patents, Columbia informed J&J of its view that, under the License Agreement, J&J is required to pay royalties on EPO made and sold in the United States even after expiration of those patents. According to Columbia, the License Agreement mandates that J&J continue to pay royalties based on its U.S. activities concerning EPO so long as there remains in force *any* patent -- anywhere in the world - - that (if applicable in the United States) would be infringed by the U.S. manufacture or sale of EPO.

29. J&J has informed Columbia that (a) the License Agreement does not require, and was never intended by the parties to require, payment of such post-patent royalties; and (b) even if the License Agreement did require such payments, it would be unenforceable under controlling U.S. Supreme Court precedent that squarely prohibits enforcement of agreements that purport to extend the life of a patent beyond its statutory term. Columbia has nonetheless persisted in the position that royalties are due based upon activities that occurred after the Axel patents expired. Indeed, as detailed below, Columbia has recently filed a vaguely worded complaint in which it asserts, *inter alia*, that J&J has breached the License Agreement by "failing to pay all amounts due and owing to Columbia . . . ."

***Columbia Sues J&J***

30. On October 31, 2003, Columbia filed a complaint in the United States District Court for the Northern District of California against J&J seeking a declaration that the '275 patent is valid and enforceable. In addition, Columbia alleges in the California action that J&J is obligated to pay royalties on products covered by the '275 patent and has breached the License Agreement by failing to pay all royalties due.



31. As of October 31, 2003, no royalties had come due under the License Agreement based on the '275 patent. Even if the '275 patent were valid and enforceable, no such royalties would be due at the present time.

**First Claim for Relief**

**(Declaration Under the License Agreement)**

32. J&J repeats and realleges paragraphs 1 through 31 above with the same force and effect as if fully set forth herein.

33. Columbia contends that, pursuant to the License Agreement between Columbia and J&J, J&J must pay royalties on account of the '275 patent. J&J contends that it has no obligation to pay such royalties because, as set forth below, the '275 patent is unenforceable and invalid. Columbia having filed its premature complaint in California, there is now an actual controversy between J&J and Columbia concerning J&J's obligations under the License Agreement.

34. J&J is entitled to and seeks a declaratory judgement that it has no obligation to pay any further royalties under the License Agreement.

35. J&J is entitled to recoup any amounts paid under the License Agreement after J&J has given notice to Columbia that it is contesting the validity and enforceability of the '275 patent. This Complaint gives such notice. Accordingly, J&J is entitled to and seeks a declaratory judgment that Columbia must repay to J&J any amounts paid under the License Agreement based on royalties paid after the Complaint has been filed.

**Second Claim for Relief**

**(Declaration of Invalidity of the '275 Patent)**

36. J&J repeats and realleges paragraphs 1 through 31 above with the same force and effect as if fully set forth herein.

37. J&J is entitled to and seeks a declaratory judgment that the '275 patent is invalid for same invention type and/or non-statutory obviousness-type double patenting because each of the claims of the '275 patent is the same as, or merely an obvious variant of, inventions claimed in the '216, '665, and/or '017 patents, either singly or in combination.

38. J&J also is entitled to and seeks a declaratory judgment that each claim of the '275 patent is invalid for failure to meet one or more of the conditions of patentability specified in the Title 35 of the United States Code, including but not limited to sections 101 and 112.

39. Upon information and belief, Columbia maintains that the '275 patent is not invalid. Accordingly, there is an actual controversy between J&J and Columbia about whether the '275 patent is invalid.

#### **Third Claim for Relief**

##### **(Declaration of Unenforceability of the '275 Patent for Prosecution Laches)**

40. J&J repeats and realleges paragraphs 1 through 31 above with the same force and effect as if fully set forth herein.

41. The '275 patent issued after unreasonable and unexplained delays in prosecution. Columbia took 22 years from the first filed application to obtain the '275 patent. In fact, it took more than nine years from the issuance of the third patent (the '017 patent) until the issuance of the fourth patent. Upon information and belief, Columbia intentionally delayed the prosecution of the '275 patent, potentially resulting in a 17-year extension on its patent monopoly. As a result of this delay, enforcement of the '275 patent has caused and will cause J&J to suffer material prejudice.

42. J&J is entitled to and seeks a declaratory judgment that the '275 patent is unenforceable due to prosecution laches.

43. Upon information and belief, Columbia maintains that the '275 patent is not unenforceable due to prosecution laches. Accordingly, there is an actual controversy between J&J and Columbia about whether the '275 patent is unenforceable due to prosecution laches.

**Fourth Claim for Relief**

**(Declaration of Unenforceability of the '275 Patent Due To Inequitable Conduct)**

44. J&J repeats and realleges paragraphs 1 through 31 above with the same force and effect as if fully set forth herein.

45. J&J is entitled to and seeks a declaratory judgment that the '275 patent is unenforceable due to inequitable conduct. In prosecuting the '275 patent, Columbia (a) advanced misleading statements to the examiner about whether its claims were patentable, (b) failed to make timely disclosure of a related application and its prosecution history, (c) failed to disclose another of Dr. Axel's patents – U.S. Patent No. 5,149,636 (the "636 patent") – and its prosecution history despite the fact that some of its claims were rejected as being anticipated or obvious in view of the '216 patent, and (d) failed to disclose statements it made to Congress that were inconsistent with positions it took during the prosecution of the '275 patent. Details of some of the instances of Columbia's inequitable conduct are set forth in greater detail in paragraphs 46 through 72 below.

46. Upon information and belief, Columbia contends that the '275 patent is not unenforceable due to inequitable conduct. As such, there is an actual controversy between J&J and Columbia concerning the unenforceability of the '275 due to inequitable conduct.

**A. Misleading Statements Regarding the Patentability of Claims of the '275 Patent**

47. The '216, '665 and '017 patents all relied upon the same original disclosure and all expired in August 2000. To overcome double-patenting rejections, Columbia filed terminal disclaimers that ended the term of the '665 and the '017 patent on the expiration date of the '216 patent.

48. During prosecution of the '275 patent, in an Office Action dated February 3, 1998, the examiner rejected all pending claims for double patenting over the issued claims of the '017 patent. These rejected claims, then numbered 126-132, were drawn to DNA constructs for transforming cells and, in the case of claim 132, eukaryotic cells transformed using such constructs.

49. In response to the February 3, 1998 Office Action, on July 24, 1998, Columbia canceled claim 132, the only claim to transformed eukaryotic cells then pending. Columbia also argued that the remaining DNA construct claims were not subject to a double-patented rejection over the '017 patent. Columbia stated: "The 'right to exclude' provided by claims 1-4 of U.S. 5,179,017 relates to transformed Chinese Hamster Ovary (CHO) cells. Thus, the 'right to exclude' provided by U.S. 5,179,017 relates only to the manufacture, use and sale of CHO cells. In contrast, the 'right to exclude' which would be provided by claims 126-131 of the subject application would, if allowed, relate to the manufacture, use and sale of DNA constructs." July 24, 1998 Response, pp. 2-3 (emphasis in original). Thus, Columbia acknowledged that the claims that issued in the '017 patent relate to transformed CHO cells.

50. During prosecution of the '275 patent, in an Amendment filed June 14, 2001, Columbia added numerous new claims, one of which ultimately issued in the '275 patent. The Remarks accompanying this amendment stated that the new claims were "not subject to the

obviousness-type double-patenting rejection." It then listed the claims in groups and explained why each group allegedly was not subject to rejection on double-patenting grounds. In each case, however, Columbia presented argument only about why the claims were not subject to double patenting in view of the '216 patent, not the '017 patent. Upon information and belief, Columbia made these statements preemptively, to deter the newly assigned examiner from issuing double-patenting rejections.

51. In asserting that the new claims in application serial No. 08/484,136 (the "'136 application") (which led to the '275 patent) were not subject to double-patenting rejections over the '216 patent, Columbia misled the PTO by failing to draw the new examiner's attention to the claims of Columbia's other patents, and most significantly the '017 patent. The claims of the '017 patent, which provided the basis for double-patenting rejections in 1998 by the examiner at that time, are substantially similar to the new claims Columbia added to the '136 application in June 2001 and would have provided a basis for double-patenting rejection of the new claims.

52. Columbia's statement that the new claims should not be rejected over the '216 patent, while failing to draw the examiner's attention to grounds for rejection over the '017 patent, was misleading because it implied that the '216 patent was the only basis upon which a double-patenting rejection could be made. Upon information and belief, in view of its statements conceding that the '017 patent relates to transformed CHO cells, Columbia was aware that the newly asserted claims, many of which were directed to transformed CHO cells, were vulnerable to double-patenting rejections over the '017 patent claims. Upon information and belief, Columbia's misleading omission of its other issued patents, particularly the '017 patent, was a deliberate and intentional effort to draw attention away from the other grounds on which the claims could be rejected for double patenting and thus to mislead the examiner.

53. Moreover, the very arguments that Columbia raised were themselves substantially false and misleading. For example, Columbia stated that certain of the new claims were not vulnerable to double-patenting rejections because "none of the claims of the '216 make obvious a recitation of "linked [DNA I and DNA II]." In fact, issued claim 54 of the '216 patent recited transforming a eucaryotic cell "with a molecule which is *formed by linking* one of the said foreign DNA I molecules to a DNA II molecule."

54. Columbia also stated that other of the newly added claims were not vulnerable to double-patenting rejections because "none of the claims of the '216 make obvious a recitation that both DNA I and DNA II are amplified." However, issued claim 54 of the '216 patent (for example) recites transforming cells with a molecule formed by linking DNA I to an amplified DNA II, and cultivating the transforming cells under conditions "permitting survival or identification of eucaryotic cells which have acquired multiple copies of said amplifiable gene." Because DNA II is an amplifiable gene linked to DNA I, the end result is both amplified DNA I and amplified DNA II. Therefore, contrary to Columbia's assertion, claim 54 does indeed make obvious a recitation that both DNA I and DNA II are amplified.

55. Columbia repeated its misleading and improper statements and omissions in its January 30, 2002 Response.

56. Upon information and belief, Columbia presented these statements with an intent to mislead the patent examiner. These misleading statements were material to the examiner's determination of patentability. The '275 patent is therefore unenforceable due to inequitable conduct in its prosecution.

**B. Failure to Disclose Rejection of Substantially Similar Claims in '159 Application**

57. On June 7, 1995, Columbia filed two continuation applications relying on the original disclosure filed in February 1980. One of these applications matured into the '275 patent. The other, serial No. 08/477,159 (the "'159 application"), is still pending today.

58. The '159 application included claims directed to subject matter that is substantially similar to the subject matter claimed in the '275 patent. For example, claim 135 of the '159 application was substantially similar to issued claim 14 of the '275 patent.

59. On April 29, 1997, the examiner then assigned to the '159 application issued an Office Action rejecting claims in the '159 application, including claim 135, for double patenting over the '017, '216 and '665 patents. The claims were also rejected for failure to satisfy 35 U.S.C. §112. Because these claims are substantially similar to claims that issued in the '275 patent, these rejections are highly material to the patentability of those claims.

60. Nonetheless, Columbia did not make the existence of the '159 application of record in the '275 prosecution until April 22, 2002, nearly seven years into the co-pendency of the two applications and a less than three months before the Notice of Allowance of the claims of the '275 patent. Even then, Columbia failed to disclose to the examiner the prior double-patenting rejections, by a different examiner in the '159 application prosecution, of claims substantially similar to those in the '275 application. This withheld information was material to the patentability of the '275 claims.

61. Upon information and belief, Columbia's unreasonable delay in disclosing the '159 application, as well as the failure to disclose rejection of substantially similar claims by a different examiner in that case, was deliberate and intentional. Therefore, the '275 patent is unenforceable due to inequitable conduct in its prosecution.

**C. Failure to Disclose the '636 Patent and Rejection of Substantially Similar Claims**

62. At about the same time or shortly after he completed the research on which the original '513 application was based, Dr. Axel collaborated with another researcher, James Roberts, to carry out further research on methods of cotransforming eukaryotic cells with foreign DNA encoding genes for producing desired proteins. Based on this research, which was closely related to the work that had led to the '216, '665 and '017 patents, Columbia filed a separate patent application on March 15, 1982. Columbia eventually abandoned this application, serial No. 358,206 (the "'206 application"), in favor of filing a continuation. It repeated this tactic twice more, ultimately receiving the '636 patent on September 22, 1992, more than a decade after it filed the initial '206 application. Columbia's '636 patent was pending during the prosecution of several of the applications that ultimately led to the '275 patent.

63. The claims of the '636 patent include claims directed to (a) processes for generating multiple copies of a foreign DNA I in eukaryotic cells and (b) eukaryotic and mammalian cells into which foreign DNA I has been introduced by the claimed processes. The claims of the '636 patent overlap in scope with at least claim 5 of the '275 patent and its dependent claims. The '636 patent was prosecuted by the same law firm that prosecuted the '216 patent and related applications (along with foreign counterparts, the "'216 patent family"), including the '275 patent.

64. Columbia never disclosed the '636 patent to the examiner or made it of record during the prosecution of the '216 patent family, although the '636 patent could have provided a basis for a double-patenting rejection of various claims in the numerous applications that led to the '275 patent. Thus, the existence of the '636 patent was material to the patentability



of claims Columbia prosecuted in the '216 patent family, including at least one claim that issued as part of the '275 patent.

65. The '636 patent file history includes rejections of claims that were substantially similar to claims that were then or later pending during prosecution of the '216 patent family, including the '275 patent. For example, claims 24 and 25 as originally filed in serial No. 06/358,206 ("206 application") (the patent application to which the '636 patent claims priority) are substantially similar to issued claim 5 of the '275 patent. Claims 24 and 25 of serial No. 06/683,251, a continuation of the '206 application, were rejected in an Office Action dated June 3, 1986 as either anticipated by or obvious in view of the '216 patent itself. This rejection, as well as others, evidenced the closeness between the '216 patent family (which included the '275 patent) and the claims Columbia was seeking in prosecuting the '636 patent. Upon information and belief, those rejections, by a different examiner, were material to the patentability of the claims asserted during the prosecution of the '216 patent family, including the claims that ultimately issued in the '275 patent.

66. Notwithstanding the more than 20 years between the filing of the application that led to the '636 patent and the issuance of the '275 patent, and the many information disclosure statements Columbia filed in the prosecution of the '216 patent family during that time period, Columbia failed to make the pendency, the issuance, or any part of the file history of the '636 patent of record in any of the applications that led to the issuance of the '275 patent.

67. As the owner of the '636 patent as well as the '275 patent, Columbia was aware of the materiality of the '636 patent and its file history to the '275 patent, as was its patent counsel, who prosecuted both the '636 and the '275 patents. Upon information and belief,

Columbia's failure to disclose the '636 patent or its file history during the prosecution of the '216 patent family was deliberate and intentional. Therefore, the '275 patent is unenforceable due to the inequitable conduct in its prosecution.

**D. Failure to Disclose Statements to Congress Inconsistent with Positions Taken Before the Patent Office.**

68. As the expiration date of the '216, '665 and '017 patents loomed, upon information and belief, Columbia embarked on an aggressive lobbying campaign in an attempt to secure from Congress an extension of the '216 patent. Upon information and belief Columbia attempted to obtain special legislation in the form of an amendment to two different, and unrelated appropriations bills. This effort proved unsuccessful.

69. Upon information and belief, Columbia made numerous statements to Congress that were inconsistent with positions it took in its concurrent prosecution of the '275 patent claims in the PTO. In its statements to Congress, Columbia emphasized the breadth and pioneering scope of the '216 patent, telling Congress that its patent broadly claimed both "cotransformed cells and the process of making them." To the PTO, on the other hand, Columbia argued that the scope of the '216 patent was much more limited. Columbia never disclosed to the PTO during prosecution of the '275 patent the inconsistent representations it made to Congress in 2000, in violation of its duty of candor to the PTO under C.F.R. § 1.56.

70. Columbia also made inconsistent representations to Congress and the PTO on other issues. For example, upon information and belief, Columbia told Congress that the '216 patent covered both linked cotransformation as well as unlinked cotransformation. With respect to linked cotransformation, Columbia told Congress that under the '216 patent, "[t]he genes of interest can be joined together in a single DNA construct prior to their introduction into the cell of interest." Columbia also asserted to Congress that "[t]he Cotransformation process [claimed

in the '216 patent] permit[s] the . . . amplification of the gene of interest for the purpose of expressing large amounts of the protein it encoded."

71. In prosecuting the '275 patent, by contrast, Columbia characterized the claims of the '216 patent far differently. Columbia stated, in June 14, 2001 and January 30, 2002 Responses to Office Actions, that "none of the claims of the '216 make obvious a recitation of 'lined' [DNA I and DNA II]." Columbia also stated that "none of the claims of the '216 make obvious a recitations that both DNA I and DNA II are amplified."

72. Thus, Columbia's assertions to Congress of the breadth of the '216 patent directly contradict its statements to the examiner of the '275 patent. Columbia never disclosed its statements to Congress to the PTO or advised the examiner that it had taken contrary positions as to the scope of the '216 claims. Upon information and belief, Columbia's failure to disclose these inconsistent statements to the PTO was deliberately misleading. Had these statements to Congress been submitted to the PTO, the examiner would have found them to be material to patentability. The '275 patent is therefore unenforceable for inequitable conduct.

#### **Fifth Claim for Relief**

##### **(Declaration of No Royalties Owed For U.S. Activities After Expiration of U.S. Patents)**

73. J&J repeats and realleges paragraphs 1-through 31 above with the same force and effect as if fully set forth herein.

74. Upon information and belief, Columbia maintains that royalties are owed under the License Agreement for activities that occurred in the United States after August 16, 2000, the expiration date of the '216, '665 and '017 patents, based upon the existence of later expiring foreign patents. J&J maintains that the License Agreement does not require payment of royalties based on activities that occurred within the United States after all valid U.S. patents had expired; that the License Agreement does not make foreign patents applicable to activities that

occur within the United States; and that any such agreement would be unenforceable in any event under controlling U.S. Supreme Court precedent.

75. J&J is entitled to and seeks a declaratory judgment that no royalties are owed under the License Agreement based upon U.S. activities that occurred after the expiration of all valid U.S. patents.

76. Upon information and belief, Columbia maintains that royalties are owed under the License Agreement based upon U.S. activities that occurred after the expiration of all valid U.S. patents. Accordingly, there is an actual case or controversy between J&J and Columbia about whether such royalties are owed.

#### **Sixth Claim for Relief**

##### **(Declaration of Unenforceability of the '275 Patent Due To Patent Misuse)**

77. J&J repeats and realleges paragraphs 1 through 31 above with the same force and effect as if fully set forth herein.

78. Columbia has demanded that J&J pay royalties under the License Agreement for activities occurring in the United States after August 16, 2000, the expiration date of the three original Axel patents. Columbia's effort to extract additional royalties based upon these patents after their expiration date constitutes patent misuse.

79. The '275 patent has an identical disclosure and derives from the same application chain as the original Axel patents. In addition, as detailed above, the claims of the '275 patent are not patentably distinct from the claims of these earlier patents. Columbia's demand for payment of royalties based on the '275 patent is part and parcel of its effort to extend its patent monopoly beyond its lawful statutory term.

80. J&J is entitled to and seeks a declaratory judgment that the '275 patent is unenforceable due to patent misuse.

81. Upon information and belief, Columbia maintains that the '275 patent is not unenforceable due to patent misuse. Accordingly, there is an actual controversy between J&J and Columbia about whether the '275 patent is unenforceable due to patent misuse.

WHEREFORE, J&J demands judgment against Columbia as follows:

- A. A judgment for J&J against Columbia on all counts of the Complaint;
- B. A declaration that J&J has no obligation to pay further royalties to Columbia under the License Agreement;
- C. A declaration that J&J is entitled to recoup all royalty payments it made under the License Agreement relating to the '275 patent;
- D. A declaration that the '275 patent is invalid and unenforceable;
- E. Permanent injunctive relief prohibiting Columbia from demanding any further royalties under the License Agreement based on the '275 patent or any pending continuations, continuations-in-part, or divisional applications of the patents recited in the License Agreement;
- F. A declaration that this is an exceptional case under 35 U.S.C. § 285;
- G. An award of reasonable attorney fees, costs and expenses; and
- F. Such other and further relief as the Court may deem just and proper.

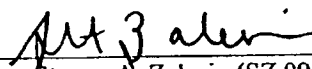
**Jury Demand**

J&J hereby demands a trial by jury on all issues triable of right by a jury in this action.

Dated: November 6, 2003

Respectfully submitted,

PATTERSON, BELKNAP, WEBB & TYLER LLP  
1133 Avenue of the Americas  
New York, New York 10036  
212-336-2000

By:   
Steven A. Zalesin (SZ 0901)  
Jeffrey I.D. Lewis (JL 8335)  
Scott B. Howard (SB 1932)

Attorneys for Plaintiff Johnson & Johnson

Of counsel:

Harman Avery Grossman, Esq.  
Johnson & Johnson